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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/032,924 | 12/26/2001 | Robert Shipman | VGEN.P-028-2 | 9912 |

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| EXAMINER | |
|---|---|
| SOUAYA, JEHANNE E | |
| **ART UNIT** | **PAPER NUMBER** |
| 1634 | |

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/032,924 | SHIPMAN ET AL. | |
| | Examiner | Art Unit | |
| | Jehanne E Souaya | 1634 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on *26 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *53-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4/02* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Oath/Declaration*

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The priority does not reflect the priority statement in the first line of the specification. Further, it does not state that the person making the oath or declaration in a CIP application filed under the conditions specified in 35 U.S.C. 120 which discloses and claims subject matter in addition to that disclosed in the prior copending application, acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56 which occurred between the filing date of the prior application and the national filing date of the CIP application.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claim 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shattuck-Eidens et al (JAMA 273, pp 535-541, 2/1995, hereinafter referred to as Shattuck-Eidens I) in view of Rossiter et al (In PCR Applications, A Practical Approach, 1991, chapter 5) and Ahern (The Scientist, vol. 9, 1995, from the internet pp 1-5).

Claims 64 is drawn to a kit comprising at least 4 PCR primers for amplifying at least 2 different exons of the BRCA1 gene in a multiplex amplification reaction.

Shattuck Eidens I teaches for testing for mutations in the BRCA1 gene. Shattuck-Eidens I teaches that one method is by direct sequencing but is labor intensive. Shattuck-Eidens teaches mutations in more than one exon of BRCA1.

Rossiter et al teach a method for detection of deletion and point mutations in a gene. Rossiter et al teach that PCR revolutionized the area of mutation detection. Specifically, Rossiter et al teach a method for detecting almost all mutations of a particular gene, involving the simultaneous amplification of individual exons using a multiplex PCR reaction and visualizing the amplified fragments by agarose gel electrophoresis. Rossiter teaches that this method provided the advantage of giving amore accurate determination of deletion end points. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to improve the method of Shattuck-Eidens I of detecting mutations in BRCA1 with the multiplex PCR method of Rossiter et al, thereby obtaining PCR primers for multiplex PCR, because Rossiter et al teach that multiplex PCR provided the advantage of giving

more accurate determination of deletion end points. The ordinary artisan would have been motivated to improve the method of Shattuck-Eidens I with the method of Rossiter et al for the purpose of making the detection of mutations in BRCA1 more accurate. Although Shattuck-Eidens I, in view of Rossiter et al do not teach packaging multiplex PCR primers for amplifying exons of BRCA1 in kit format, Ahern teaches that packaging reagents in kit format saves researchers time (see pp 4 and 5). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to package the primers of Shattuck-Eidens I in view of Rossiter et al, in kit format, as taught by Ahern, for the purpose of making the method of Shattuck-Eidens I in view of Rossiter et al easier to perform.

5. Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shattuck-Eidens et al (JAMA 273, pp 535-541, 2/1995, hereinafter referred to as Shattuck-Eidens I) in view of Rossiter et al (In PCR Applications, A Practical Approach, 1991, chapter 5) and Ahern (The Scientist, vol. 9, 1995, from the internet pp 1-5) as applied to claim 64 above, and further in view of and Shattuck-Eidens et al (US Pat 5,693,473; hereinafter referred to as Shattuck-Eidens II) and Kozlowski et al (Nucleic acids Research, vol. 24, 1996; pp 1177-1178).

The teachings of a kit of Shattuck-Eidens I, in view of Rossiter et al and Ahern et al is set forth above. Together, Shattuck-Eidens I and Shattuck Eidens II teach mutations in exons 2,4,5,9,11,13,15,16,18,20,21,and 24 of BRCA1. Kozlowski et al teach mutations in exon 14 of BRCA1. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made improve the kit of Shattuck-Eidens I in view of Rossiter et al and Ahern, to develop primers for multiplex PCR amplification of different exons, or regions of

exons, of BRCA1 for the purpose of accurately detecting all mutations of BRCA1. It would have been obvious to develop a kit for detecting mutations in exons 2,5,9, and 14, as well as to different combination of other exons containing mutations, as mutations in such exons of BRCA1 were known at the time of the invention, as illustrated by the teachings of Shattuck – Eidens I and II, and Kozlowski et al. The ordinary artisan would have been motivated to package such primers in kit format because Shattuck-Eidens I and II and Kozlowski teach that mutations in such exons exist and that mutations in BRCA1 are linked to cancer.

***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 53-65 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 6,403,303. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '303 patent are drawn to methods and kits which are coextensive in scope with the methods and kits of the instant application. The claims of the '303 patent are more specific than the instant claims in that they recite specific exons of BRCA1 or specific primers, however

the instant claims are obvious over the claims of the '303 patent, although more general. For example, claim 16 of the '303 patent is drawn to a kit comprising primers for testing for mutations in BRCA1 and cite specific exons and primers for use in the kit. Claims 64 and 65 of the instant application are more general (claim 64 is drawn to primers for any exon; claim 65 is drawn to specific exons as in claim 16 of the '303 patent), however are obvious over the disclosure of claim 16 of the '303 patent. The same analysis applies for the method claims (53-63).

***Conclusion***

8. No claims are allowable.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703) 308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya
Primary Examiner
Art Unit 1634
9/29/03